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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
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| 1634 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 08/974,584 | CECH ET AL. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *119,129 and 130* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119,129 and 130* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2007 has been entered.

2. Applicant's arguments and amendments to the claims set forth in the response of July 27, 2007 have been fully considered. All rejections not reiterated herein are hereby withdrawn. In particular, the obviousness-type double patenting rejection of claims 119, 129 and 130 over U.S. Application Serial No. 09/721,477 is withdrawn in view of Applicants arguments regarding the fact that the claims in the '477 application have been amended to recite a polynucleotide encoding a hTRT polypeptide that is catalytically inactive.

Claims 119, 129 and 130 are pending and have been examined herein.

This action contains new grounds of rejection and is made non-final.

### Terminal Disclaimer

3. The terminal disclaimer filed on July 27, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any

patent granted on U.S. Patent application Nos. 10/877,124, 09/721,506 and 11/207,078 has been reviewed and is accepted. The terminal disclaimer has been recorded.

**Information Disclosure Statement**

4. In the Information Disclosure Statement filed July 27, 2007, the citations listed under "Non-Patent Literature Documents" as AU-CE have been considered but have been lined through since the cited patent claims and claims for pending applications do not constitute non-patent literature.

**New Grounds of Rejection**

**Claim Rejections - 35 USC § 112 – Written Description**

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119 and 129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

In analyzing the claims for compliance with the written description requirements of 35 U.S.C. 112, first paragraph, a determination is made as to whether the specification contains a written description sufficient to show they had possession of the full scope of their claimed invention at the time the application was filed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof.

Thereby, to ascertain whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. It is then determined whether a representative number of species have been defined by other identifying characteristics.

In the present situation, the claims are drawn to a recombinant or synthetic polynucleotide encoding a protein that comprises an amino acid sequence that is at least 60% identical to SEQ ID NO: 118 (claim 119) or at least 80% identical to SEQ ID NO: 118 (claim 129), wherein said protein further includes the sequences of either SEQ ID NO: 16 or 17; SEQ ID NO: 139, SEQ ID NO: 143, SEQ ID NO: 144, SEQ ID NO: 146, and SEQ ID NO: 147, and wherein said protein has telomerase catalytic activity when complexed with a telomerase RNA component.

SEQ ID NO: 118 consists of 1132 amino acids. Thereby, polynucleotides sharing only 60% or 80% with the 1132 amino acids of SEQ ID NO: 118 (while including the above stated sequence motifs) encompasses a very large genus of polynucleotides encoding polypeptides that have not been clearly defined in terms of their overall structural properties. Such polynucleotides include polynucleotides encoding for TRT

proteins isolated from non-human species, as well as mutant and polymorphic variants of TRT from any human or non-human species.

The specification teaches a polynucleotide encoding the human telomerase reverse transcriptase (hTRT) protein of SEQ ID NO: 118. The specification further teaches polynucleotides encoding TRT proteins from Euplotes aediculatus, Oxytricha, Saccharomyces cerevisiae, Tetrahymena, and Schizosaccharomyces pombe. However, these polynucleotides encode for polypeptides that share less than 60% identity with SEQ ID NO: 118 and thereby these polynucleotides are excluded by the claims. The specification also teaches a polynucleotide encoding mouse TRT, wherein the polynucleotide consists of SEQ ID NO: 124 and has 62% identity with SEQ ID NO: 118. However, the claims are not inclusive of this polynucleotide because claim 119 specifically excludes the polynucleotide of SEQ ID NO: 124 and claim 129 excludes polynucleotides encoding for polypeptides having less than 80% identity with SEQ ID NO: 118. The specification (pages 37-38) also teaches a variant of hTRT consisting of SEQ ID NO: 117 and having a 182bp deletion. This polypeptide is described in the specification as "unlikely to encode a fully active telomerase catalytic enzyme." Thereby, the polynucleotide of SEQ ID NO: 117 does not appear to be encompassed by the claims.

The specification also provides an alignment of TRT proteins and identifies regions within these protein sequences that are conserved amongst TRT proteins (i.e., SEQ ID NO: 16 or 17,SEQ ID NO: 139, SEQ ID NO: 143, SEQ ID NO: 144, SEQ ID NO: 146, and SEQ ID NO: 147). The specification further teaches the general methodology

for using known TRT nucleic acids to identify and isolate additional homologues and mutants of TRT nucleic acids.

However, possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See University of Rochester, 358 F.3d at 927, 69 USPQ2d at 1895.

This finding is also emphasized in *Ex Parte Kubin* (No. 2007-0819, Bd. Pat. App. & Int. May 31, 2007), wherein it is stated that :

"Although there is often significant overlap" between the enablement and written description requirements, "they are nonetheless independent of each other." University of Rochester, 358 F.3d at 921, 69 USPQ2d at 1891. An "invention may be enabled even though it has not been described." Id. Such is the situation here. While we conclude one skilled in the art would have been able to make and use the full scope of claim 73 through routine experimentation, we find Appellants did not describe the invention of claim 73 sufficiently to show they had possession of the claimed genus of nucleic acids. See, e.g., Noelle v. Lederman, 355 F.3d 1343, 1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004) ("invention is, for purposes of the 'written description' inquiry, whatever is now claimed").

Thereby, a showing of how to potentially identify and make other TRT proteins is not sufficient to establish that Applicant's were in possession of the invention as broadly claimed.

Accordingly, the specification has described by its complete structure only one polynucleotide encoding a polypeptide having telomerase activity when complexed with a RNA component of telomerase – i.e., the polynucleotide encoding SEQ ID NO: 118.

No additional members of the claimed genus have been sufficiently described in terms of any other relevant identifying characteristics. While the specification teaches regions of TRT that are conserved between species (i.e., SEQ ID NO: 16 or 17,SEQ ID NO: 139, SEQ ID NO: 143, SEQ ID NO: 144, SEQ ID NO: 146, and SEQ ID NO: 147), these sequences alone do not impart the functional activity of a telomerase reverse transcriptase activity onto the protein. Telomerase proteins from different organisms show high levels of sequence variability. Given this high level of variability, it is clear that the presence of the conserved regions alone are not sufficient to impart telomerase activity. Yet, the specification does not teach which additional sequences in the overall structure of TRT are critical for telomerase catalytic activity. That is, which sequences in the regions flanking SEQ ID NO: 16 or 17,SEQ ID NO: 139, SEQ ID NO: 143, SEQ ID NO: 144, SEQ ID NO: 146, and SEQ ID NO: 147 are essential for telomerase catalytic activity. It is well known in the art that even a single conservative amino acid substitution can adversely effect the proper folding and biological activity of a protein if the amino acids are critical for functional activity. While one may identify conserved amino acid regions of a protein, such information does not allow one to ascertain which amino acids will effect the tertiary structure of the protein and thereby the overall functional activity of the protein. There is no clear disclosure in the specification of the effect of an amino acid substitution, deletion or addition on the activity of the claimed TRT proteins.

Thereby, while the specification discloses conserved domains in TRT proteins, this information is not sufficient to fully characterize the structure-function relationship between TRT sequences and TRT catalytic activity.

Again, the claimed genus is significantly large including any polynucleotide encoding a homologue, splice, deletion, insertion or naturally or non-naturally occurring allelic variant having 60% or 80% identity with SEQ ID NO: 118. Yet, the specification teaches only one polynucleotide encompassed by the claimed genus. In the absence of a representative number of species of the claimed genus, there is insufficient descriptive support for the currently claimed genus of recombinant polynucleotides encoding a hTRT polypeptide.

The decisional law in this area has been very consistent. The Federal Circuit in Lilly, Fiers, Rochester and many other cases has determined that the written description issue applies to situations where the definition of the subject matter of the claims fails to provide description commensurate with the genus. The most recent case law directly supports this rejection. As the District Court in University of Rochester v. G.D. Searle & Co., Inc. (2003 WL 759719 W.D.N.Y.,2003. March 5, 2003.) noted "In effect, then, the '850 patent claims a method that cannot be practiced until one discovers a compound that was not in the possession of, or known to, the inventors themselves. Putting the claimed method into practice awaited someone actually discovering a necessary component of the invention." This is similar to the current situation since the breadth of the current claims comprises polynucleotides encoding TRT polypeptides which the present inventors were not in the possession of, or which were not known to the

inventors. In a genus that is possibly quite immense, the specification discloses only a limited number of embodiments – that is the polynucleotides encoding SEQ ID NO: 118.

As noted in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), the Federal Circuit concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision.

With respect to the present invention, there is no record or description which would demonstrate conception of any recombinant polynucleotides encoding a TRT polypeptide other than those expressly disclosed as encoding SEQ ID NO:118. Therefore, the claims fail to meet the written description requirement because the claims encompass a significantly large genus of polynucleotide sequences which are not described in the specification. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 'Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, and particularly Example 14 (http://www.uspto.gov/web/menu/written.pdf).

**Double Patenting**

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119, 129 and 130 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 71-74, 76, 77, and 79-82 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '078 are both inclusive of nucleic acids encoding the human telomerase reverse transcriptase of SEQ ID NO: 118 (referred to in '692 as SEQ ID NO: 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that this rejection was previously set forth on page 6 of the Office action of October 13, 2006 and has been modified in view of the amendments to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/
Primary Examiner, Art Unit 1634